UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,102	06/02/2005	Juha Kuja-Panula	0933-0246PUS1	2142

2292 7590 10/18/2007

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
10/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,102	KUJA-PANULA ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *1-6,8-19,21-61,63 and 64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,20 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed on August 6, 2007 is acknowledged. Claims 7, 20, 58 are amended. Claims 62-64 are newly added. Claims 1-61 and newly added claims 62-64 are pending in this application. Claim 58 as amended is directed to a method of treating a disease using a pharmaceutical composition comprising an AMIGO ectodomain fragment or an antibody, which is grouped to non-elected Group VII (see the restriction requirement mailed on 9/8/06. In addition, new claims 63-64 are directed to a method of producing a human AMIGO ectodomain fragment, which is independent or distinct from the invention originally claimed. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 1-6, 8-19, 21-58, 59-61, 63-64 are withdrawn with traverse (response filed on 1/8/07) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. See 37 CFR 1.142(b) and MPEP § 821.03. Applicant timely traversed the restriction (election) requirement in the reply filed on Jan 8, 2007.

2. Claims 7, 20, 62 are under examination with respect to a polypeptide of SEQ ID NO:2 in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on August 6, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 20 and 58 under 35 U.S.C.§ 112, first paragraph, as failing to meet the written description requirement is withdrawn in response to Applicant's amendment to the claims and withdrawal of claim 58 from consideration.

Claim Rejections/Objections Maintained

6. Claims 7, 20 stand objected to as encompassing non-elected inventions (i.e. antibody) and non-elected sequences (SEQ ID NOs: 4 and 6). The objection is maintained of record.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The rejection is maintained for the reasons made of record in the office action mailed on 4/5/07, and as follows.

At p. 20 of the response, Applicant argues that claim 20 is enabled because it has been amended to recite a pharmaceutical composition comprising aa 1-371 of SEQ ID NO:2 or an antibody binding to aa 1-371 of SEQ ID NO:2 and the specification on p. 84 supports such amendment to enable a skilled artisan as to how to make and use the claimed pharmaceutical composition based on Exhibits 1-2. Applicant's arguments have been fully considered but they are not persuasive.

In contrast to Applicant's assertion, the specification provides no enabling disclosure to enable one of skill in the art to practice the claimed pharmaceutical composition. First, no support of a pharmaceutical composition comprising aa 1-371 of SEQ ID NO:2 can be found in the specification (i.e. note that the subject mater related to an antibody is withdrawn from consideration as it is directed to a non-elected group, which will not be discussed in this office action). The recitation of an isolated polypeptide comprising aa 1-371 of SEQ ID NO:2 is considered as new matter because no support can be found in the specification. Second, although the specification teaches that the soluble form of the ectodomain of AMIGO has inhibitory effects on neurite outgrowth and fasciculation, the specification fails to teach whether and how such soluble form of the ectodomain of AMIGO can be used to treat any undefined disease. Different neurodegenerative diseases and neuropathological conditions have different causes that may not be associated with each other. The specification fails to provide sufficient guidance as to enable one of skill in the art to use the claimed pharmaceutical

composition for any disease treatment. Thus, a skilled artisan cannot contemplate how to use the claimed pharmaceutical composition.

"The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., Chiron Corp. v. Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004)"

At p. 21-22 of the response, Applicant argues that the specification provides teachings to predict which diseases would be treatable by the claimed composition and methods of treatment on p. 42-46, 47-49 and p. 60, 65, 67 and 91-103 because the claimed composition would inhibit EGFR and could be used in diseases characterized as aberrant growth, migration, regeneration or proliferation of cells that express an AMIGO receptor. Applicant's arguments have been fully considered but they are not persuasive.

In contrast to Applicant's assertion, the specification fails to provide sufficient guidance as to how to use the claimed pharmaceutical composition comprising aa 1-371 of SEQ ID NO:2 to treat any undefined disease including different neurodegenerative diseases and neurological conditions with non-related causes or any disease with aberrant growth, migration, regeneration or proliferation of cells that express an AMIGO receptor. The specification does not teach what diseases associated with aberrant growth, migration, regeneration or proliferation cells that express AMIGO receptors are and can be treated by the claimed composition. Although

phosphorylation of EGFR has been shown to be involved in tumor development, EGF/EGFR activity is also essential for neural survival and development. Thereby, it is unpredictable whether blocking the activity of EGF/EGFR would block the normal activity of EGFR for neural survival or development. The specification fails to teach how to use the claimed pharmaceutical composition in treatment of an undefined disease without affecting normal neural survival or development. Applicant provides insufficient guidance as to how to regulate the blocking activity of EGFR without affecting the normal activity of EGFR in normal neural development in vivo by the claimed composition comprising aa 1-371 of SEQ ID NO:2. Thus, it is unpredictable whether a pharmaceutical composition comprising aa 1-371 of SEQ ID NO:1 can be used in treatment of an undefined disease.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, it is unpredictable whether the claimed pharmaceutical composition comprising aa 1-371 of SEQ ID NO:2 can be used for any treatment of any disease; and the experimentation left to those skilled in the art is extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed invention as currently claimed without further undue experimentation. Accordingly, the rejection of claim 20 under 35 U.S.C. §112, first paragraph, because the specification does not enable the claimed invention is maintained.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Shimkets et al. (WO200070046, published on Nov 23, 2000). The rejection is maintained for the reasons made of record in the office action mailed on 4/5/07, and as follows.

At p. 25 of the response, Applicant argues that Shimkets (WO'046) does not teach any function for AMIGO1 and does not anticipate a functional ectodomain of AMIGO peptide fragment consisting of amino acid residues (aa) 1-371 of SEQ ID NO:2 because Shimkets (WO'046) does not teach any functional or structural importance to this specific ectodomain comprising aa 1-371 of SEQ ID NO:2. Applicant further cites *Verdegaal Bros. v. Union Oil Co of California* in support of the arguments related to anticipation by the prior art reference. Applicant's arguments have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., function of AMIGO or functional or structural importance to the ectodomain) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In addition, in contrast to Applicant's assertion that Shimkets (WO'046) does not anticipate the claimed peptide, the examiner asserts that Shimkets (WO'046) anticipates the claimed peptide as recited in claims 7 and 20 because the recitation of "comprising aa 1-371 of the amino acid sequence of SEQ ID NO:2 in claim 7 also reads on the full length of SEQ ID NO:2 and any fragments or polypeptides "comprising at least aa 1-371 of SEQ ID NO:2". Since only limited structural limitation and no functional limitation are recited in the claims, an isolated ectodomain fragment of AMIGO polypeptide comprising aa of 1-371 of the amino acid sequence of SEQ ID NO:2 encompasses any fragments of SEQ ID NO:2 having the amino acid sequence containing at least aa 1-371 of SEQ ID NO:2 or the full length of SEQ ID NO:2, which are anticipated by Shimkets (WO'046), as previously made of record.

Lastly, since the structure of the amino acid sequence meets the limitation of the claimed peptides or fragments, the functional activity of the claimed peptides would be an inherent feature of the peptides or fragments; absent evidence to the contrary since the activity of the polypeptide is determined by the structure and the composition of the amino acid sequence. Since no defined functional limitation recited in the claimed peptide, the polypeptide disclosed in Shimkets (WO'046) anticipates the claimed peptide because the amino acid sequence of Shimkets' (WO'046) polypeptide meets the limitation of the amino acid sequence of the claimed peptide, which comprising aa 1-371 of SEQ ID NO:2.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 20 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims as amended are directed to a polypeptide comprising or consisting of amino acids 1-371 of SEQ ID NO:2 and a pharmaceutical composition comprising the claimed polypeptide. The instant claims now recite a limitation of amino acids 1-371 of SEQ ID NO:2, which was not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitation recited in the present claims, which did not appear in the specification or original claims, as filed, introduces new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant fails to disclose amino acids 1-371 of SEQ ID NO:2 as recited in the claims. The specification fails to disclose the limitation of amino acids 1-371 of SEQ ID NO:2. Applicant only discloses SEQ ID NO:2 and an ectodomain of AMIGO but fails to

specify amino acid residues of an ectodomain of AMIGO in the specification. Accordingly, in the absence of sufficient recitation of amino acid residues 1-371 of SEQ ID NO:2, the specification does not provide adequate written description to support amino acids 1-371 of SEQ ID NO:2 as recited in the claims. Although Applicant states that support of claim amendment can be found at p.84 of the specification (see p.18 of the response), no such support can be found. Since support is not found for amino acids 1-371 of SEQ ID NO:2 as disclosed in the original specification, the recitations constitute new matter absent evidence for their support. Applicant is required to cancel the new matter in the reply to this office action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

Conclusion

10. NO CLAIM IS ALLOWED.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
October 3, 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud